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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/583,979	06/22/2006	Richard Ross	7730-75922-01	8414

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EXAMINER	
SZNAIDMAN, MARCOS L	
ART UNIT	PAPER NUMBER
1612	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/583,979	ROSS, RICHARD	
	Examiner	Art Unit	
	MARCOS SZNAIDMAN	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 February 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,7-21,25-27 and 31* is/are pending in the application.

4a) Of the above claim(s) *9-21,25-27 and 31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,7 and 8* is/are rejected.

7)☒ Claim(s) *3* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2 pages, June 22, 2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This office action is in response to applicant's reply filed on February 27, 2009.

Election/Restrictions

Applicant's election of Group I (Claims 1-4 and 7-18) and the species "depression" in the reply filed on February 27, 2009 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a).

Status of Claims

Claims 1-4, 7-21, 25-27 and 31 are currently pending and are the subject of this office action.

Claims 9-21, 25-27 and 31 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions/species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on February 27, 2009.

Claims 1-4 and 7-8 are presently under examination.

Priority

The present application is a 371 of PCT/GB04/05418 filed on 12/30/2004, and claims priority to foreign application: UNITED KINGDOM 0400031.1 filed on 01/03/2004.

Information Disclosure Statement

The Information Disclosure Statement filed on June 22, 2006 is acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner. A signed copy of the IDS is attached hereto.

Claim Objections

Claim 3 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 3 recites the method of claim 1, wherein the animal has depression. However depression is already a limitation in claim 1.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 2 and 7-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2 and 7-8 recite the limitation "condition (that results in depression)". There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, and 3-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over DeBattista (Am. J. Psychiatry (2000) 157:13341337, cited by Applicant) in view of Ross et. al. (WO 2003/015793, cited by Applicant) as evidenced by Stedman's (Stedman's Medical Dictionary, 27 Edition (1999), pages 477-478).

Claims 1 and 3 recite a method of treating depression, comprising administering to the animal a composition comprising hydrocortisone and a delivery vehicle wherein said delivery vehicle provides for delayed and sustained release of hydrocortisone and wherein the vehicle is adapted for oral delivery.

Claim 4 further limits claim 3, wherein the depression is clinical depression, reactive depression or post-natal depression.

For claims 1 and 3-4 DeBattista teaches a method of treating major depression (see first line on page 1334. Major depression is a synonym of clinical depression as evidenced by Stedman's (see page 477 for a definition of depression and page 478 for a definition of clinical depression)) comprising administering hydrocortisone which was administered intravenously for periods of two hours (see title, procedure and results on page 1335, and first paragraph under discussion on page 1336).

De Battista does not teach a vehicle that provides for delayed and sustained release of hydrocortisone that is adapted for oral delivery. However, Ross teaches pharmaceutical compositions comprising a therapeutic agent and a delivery vehicle characterized in that the delivery vehicle provides for the delayed and sustained release

of the therapeutic agent (see page 7, lines 1-4). In a preferred embodiment of the invention the therapeutic agent comprises hydrocortisone (see page 7, lines 6-7, see also page 6 line 10) and the therapeutic agent can be administered by oral route (see page 7, line 14).

At the time of the invention, it would have been *prima facie* obvious for a person of ordinary skill in the art to treat major depression with a composition comprising hydrocortisone as taught by DeBattista, with a vehicle that provides delayed and sustained release of hydrocortisone and that is adapted for oral delivery as taught by Ross, with the motivation of obtaining a better formulation and hence a more effective treatment of depression, since Ross teaches that this type of formulation produces better pharmacokinetic profiles (see Examples 1-7 on pages 15-27), thus resulting in the practice of claims 1 and 3-4 with a reasonable expectation of success.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 and 3-4 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 31-37 of copending Application No. 10/486,700 in view of DeBattista (Am. J. Psychiatry (2000) 157:13341337, cited by Applicant).

The copending Application teaches a method of administering hydrocortisone to humans in a formulation containing a vehicle which is adapted for delayed and sustained release of hydrocortisone. The copending Application does not teach the treatment of clinical depression (major depression) with a formulation of hydrocortisone. However DeBattista teaches the treatment of major depression with a formulation of hydrocortisone.

At the time of the invention, it would have been *prima facie* obvious for a person of ordinary skill in the art to treat major depression with a composition comprising hydrocortisone as taught by DeBattista with a vehicle that provides delayed and sustained release of hydrocortisone as taught by de copending application with the motivation of obtaining a better formulation and hence a more effective treatment of depression, thus resulting in the practice of claims 1 and 3-4 with a reasonable expectation of success.

This is a provisional obviousness-type double patenting rejection.

Conclusion

No claims are allowed.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARCOS SZNAIDMAN whose telephone number is (571)270-3498. The examiner can normally be reached on Monday through Thursday 8 AM to 6 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MARCOS SZNAIDMAN/
Examiner, Art Unit 1612
June 10, 2009

/Frederick Krass/

Supervisory Patent Examiner, Art Unit 1612